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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	PATWA-2	5150

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/469,606

Applicant(s)

VOLLMERS ET AL.

Examin r

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2001 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Please note the Examiner of record has changed. Contact information is provided at the close of this action.

2. Claims 1-37 are pending.

Claims 5-7, 9-20 and 23-25 have been amended.

Claims 30-37 have been added.

Claims 5-37, drawn to non-elected inventions are withdrawn from consideration.

Claims 1-4 are examined on the merits.

3. Newly submitted claims 30-37 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 30-34 are drawn to a method as presented in Group III (original claims 7, 9, 23 and 25), see Restriction/Election requirement, Paper number 6, mailed November 21, 2000. And while the product of Invention I and the method of Invention III are related as product and process of use, the product as claimed can be practiced with another materially different process (MPEP § 806.05(h)).

Claims 35-37 are drawn to a product as presented in Group V (original claims 14-16). This product is drawn to a pharmaceutical composition comprising an agent, which binds specifically to a glycoprotein. These claims are not commensurate in scope to the product claims of Group I, hence is not a member of that restriction group as further exemplified by their different classification.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

4. Applicants have obtained the benefit of foreign priority under 35 U.S.C. 119(a)-(d) in light of the translations submitted December 26, 2001 of the foreign applications under 37 CFR 1.55 in reply to the action mailed July 3, 2001 as Paper number 9. Accordingly, the instant application is afforded the priority date of December 22, 1998.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claims 2 and 4 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of Applicants' submission of a declaration under 37 CFR 1.132.

6. The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 102

7. The rejection of claims 1-4 under 35 U.S.C. 102(a) as being anticipated by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS) is withdrawn in light of Applicants' new established priority date.

Maintained and New Grounds of Rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants broadly claim an isolated glycoprotein that comprises at least one section of the amino acid primary structure of CD55 and a tumor-specific glycostructure. However, Applicants have not assigned a sequence identifying number to the protein, nor described the structure or the section of the amino acid that supports the activity of the protein. Applicants are not entitled to all proteins capable of exhibiting this structure or containing the amino acid primary structure of CD55. Applicant is only in possession of one species, which is not identified by a sequence identity number or explicitly

defined by structure. The specification does provide details of the glycoprotein such as the 82kD molecular weight of the protein and that it must be reactive with antibody, SC-1 as stated in the claims (see page 5, first full paragraph). But as claim 1 reads it also encompasses a glycoprotein that may be a variant containing deletions, insertions and/or substitutions as further exemplified in the said section of the specification. Applicants are not permitted to claim all proteins that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue.

Claim Rejections - 35 USC § 102

10. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Medof et al. (J. Exp. Med. 160:1558-1578, 1984), as evidence by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS) is maintained.

Applicants argue that "[t]he difference between the glycoproteins of the instant claims and the reference[s] is evidenced... by ...different molecular weights." Additionally, Applicants assert that the glycoprotein of Medof is isolated from human red cells and has a molecular weight of 70,000 unlike Applicants. These arguments are not found persuasive.

Applicants are arguing limitations that are not in claims 1 and 2, hence the reference continues to read on Applicants' glycoprotein. Clearly the DAF protein of Medof, possesses the inherent property of binding the SC-1 monoclonal antibody is the same as that claimed. Applicants have not provided any objective evidence that would persuade one of ordinary skill in the art that the disclosed glycoprotein of Medof is not

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the same as that claimed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the glycoproteins of the Applicants' with the proteins of the patent the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the antibodies in the claimed invention to be used in the claimed methods of the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

11. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Tsuji (U.S. Patent number 5,695,945, issued December 9, 1997), as evidence by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS) is maintained.

Applicants argue are that "[t]he difference between the glycoproteins of the instant claims and the reference[s] is evidenced... by ...different molecular weights" even though the molecular weight of Tsuji's protein is not disclosed in the reference. Furthermore, they argue that the glycoprotein of the patent is isolated from (non-tumor) human blood and the glycoprotein of the reference lacks material elements of the claimed glycoprotein. This is not found persuasive for the reasons of record as stated above and in the first action on the merits, Paper 9, page 8, paragraph 8. Since the Patent and Trademark Office does not have the facilities for examining and comparing the glycoproteins of the Applicants' with the proteins of the patent the burden of proof is upon the Applicants to show an unobvious distinction between the structural and

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functional characteristics of the antibodies in the claimed invention to be used in the claimed methods of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
March 10, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600